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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,591	12/05/2001	Katherine S. Bowdish	1087-3	3521

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EXAMINER	
LAMBERTSON, DAVID A	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,591	BOWDISH ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) *7-22,38-72 and 75-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,23-32,37,73 and 74* is/are rejected.

7)☒ Claim(s) *33-36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1-6,23-37 and 73-74) in the response filed October 1, 2003 is acknowledged. The traversal is on the ground(s) that a search of Group I as set forth in the Restriction requirement would necessarily result in a search of Groups II-IV as well. This is not found persuasive because of the following reasons:

Group I was indicated in the Restriction requirement as being separate from Group II because Group I can be used to perform different methods than those set forth in Group II. For instance, Group I can be used in a conventional cloning technique, as opposed to the particular one claimed in Group II. Therefore, identification of art relating to Group I would not necessarily result in art relating to Group II, hence a separate and burdensome search would be required to search both Groups I and II. Group I was indicated in the Restriction requirement as being separate from Group III because Group I was a distinct chemical molecule that was not an obvious variant of the molecule claimed in Group III. Furthermore, applicant failed to indicate that the molecules set forth in Groups I and III are indeed obvious variants in view of each other, therefore indicating that a separate and burdensome search would be required to search both groups. Finally, Group I and Group IV were indicated as being distinct because the proteins of Group IV could be manufactured by methods that did not require the use of the nucleic acids set forth in Group I, and were therefore unrelated. As a result of this non-relatedness, a search of both groups would be burdensome because it would require

distinct searches (i.e., one for a particular nucleic acid sequence, and one for an amino acid sequence).

Applicant has not provided an argument with substantial grounds to vacate the previous restriction requirement. Furthermore, the groups were indicated as having distinct class/sub-classes associated with them, thereby indicating that a patent search would require multiple searches. As applicant has provided no other evidence to link the inventions of Groups I-IV, the restriction requirement is upheld.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-84 are pending in the instant application. Claims 7-22, 38-72 and 75-84 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-6, 23-37 and 73-74 are ready for consideration in the instant application.

Priority

Applicant's claim for domestic priority to US Application 60/251,440 under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

The information disclosure statements filed June 3, 2002 and August 18,2003 have been considered, and a signed and initialed copy of each form PTO-1449 is attached to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase: "the second portion of the nucleic acid encoding a polypeptide being at least 20 nucleotides removed from the first portion of the nucleic acid," etc. This phrase is indefinite because it is unclear if the second portion of the nucleic acid is actually a duplication of 20 nucleotides from the first portion of the nucleic acid (i.e., 20 nucleotides are removed from the first portion and used to construct the second portion, thereby establishing a region of homology between the two portions), or if the second portion is located at least 20 nucleotides downstream (i.e., in the 5' to 3' direction) from the first portion. This is especially important in view of the nature of the invention (i.e., where annealing and possible recombination of nucleic acids must be considered). In the interest of compact prosecution, the claim is interpreted as if the latter suggestion set forth above was representative of the claim. It would be remedial to change the language of the claim to read similar to: "wherein the second portion of the nucleic acid encoding a polypeptide is at least 20 nucleotides downstream from the first portion of the nucleic acid," etc.

The term "remote" in claim 5 is a relative term which renders the claim indefinite. The term "remote" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would

not be reasonably apprised of the scope of the invention. In this instance, the term "remote" is indefinite because it is unclear how near/far the first and second portions of the nucleic acid must be in ordered to be considered "remote" with respect to each other. As such, the claim is indefinite because it is impossible to adequately search for the presence or absence of such a limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Hornes *et al.* (WO 91/07505; IDS reference; see entire document; henceforth Hornes).

Hornes teaches a plasmid for use in a cloning method that eliminates the need for conventional cloning techniques. The plasmid is linearized in a manner such that it has terminal regions with significant homology to a target DNA (see for example the paragraph bridging pages 2-3). These terminal regions are analogous to the primer and collar regions set forth in the instant claims because they meet the function limitation of annealing to a nucleic acid of interest. Significantly, these regions of homology can be present in the target nucleic acid endogenously, or can be placed there artificially (see for example page 3, third full paragraph). The cloning method described includes a method by which direct cloning of cDNA sequences is accomplished (see for example the

paragraph bridging pages 8-9). Importantly, there is more than 20 nucleotides between the first and second portions of the target nucleic acid because the specific target exemplified by Hornes, the *apoE* gene (see for example page 17, first full paragraph), is completely cloned in the method, and is greater than 20 nucleotides in length; therefore the homology regions must be greater than 20 nucleotides in length in order to clone the whole gene. Finally, the vector contains at least two restriction enzyme sites between the regions of homology with which the vector is linearized; in the instant example, the pUC18 vector is linearized with both *Eco*RI and *Hin*dIII prior to its use in the cloning procedure (see for example the paragraph bridging pages 16-17). Therefore, Hornes anticipates each of the claims set forth above.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 23-32, 37, 73 and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhu *et al.* (US Patent 6,610,472; see entire document; henceforth Zhu).

Zhu teaches a method of recombinational cloning to generate an expression library, in particular an antibody expression library. The method involves the use of a linearized expression vector to clone a nucleic acid fragment of interest by recombination. The vector has both a 5' and 3' terminal sequence when linearized, each of which is homologous to the terminal sequences of the target nucleic acid (see for example column 5, lines 57-63). These homologous sequences result in a recombination event that results in the incorporation of the sequence of interest into the vector (see for

example column 5, lines 64-66). In particular, the sequence of interest can be any antibody sequence (for example, an antibody heavy-chain variable region, light-chain variable and constant region, etc.-see for example column 19, lines 30-46), and the sequence can be either in the form of an mRNA molecule or a cDNA molecule encoding the antibody (see for example column25, line 63 to column 26, line 23). Significantly, the vector sequence in this situation also has up to 2 restriction sites between the regions of homology, which can be cut with the appropriate restriction endonuclease in order to increase the annealing/recombination process (see for example column 24, lines 7-19; column 29, lines 10-34; Figures 2 and 3). Finally, the cloning of full antibody sequences (as performed in Example 1 of the Zhu reference) requires that the regions of homology be at least 20 nucleotides apart in order to fully clone the target region. Therefore, Zhu anticipates each of the claims set forth above.

Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone

number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
AU 1636

JAMES KETTER
PRIMARY EXAMINER